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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WHISENANT, ETHAN C	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,258	LEXOW, PREBEN	
	Examiner	Art Unit	
	Ethan Whisenant, Ph.D.	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2006 and 27 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-17 and 19-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15 and 19-24* is/are rejected.

7)☒ Claim(s) *16 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

NON-FINAL ACTION

1. The applicant's response (filed 17 FEB 06) to the Office Action has been entered. Following the entry of the claim amendment(s), **Claim(s) 15-17 and 19-24** is/are pending. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

35 USC § 112- 2nd Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

3. **Claim(s) 15-17, 19-24** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are indefinite in view of the phrase "binary alphanumeric code". It is unclear what is intended. The examiner is aware of binary code (e.g. 0 and 1) commonly used in computer technologies and with alphanumeric code e.g. a series of letters and numbers which are written in a form understandable and processible by a computer. One such alphanumeric code is ASCII. It is unclear to the examiner as to the metes and bounds of what is intended by the phrase "binary alphanumeric code". This phrase is not defined in the specification. Furthermore, in Claim 16 the applicant refers simply to the alphanumeric code. Please clarify.

CLAIM REJECTIONS UNDER 35 USC § 102

4. Claim(s) 15, 19-21, and 23 is/are rejected under 35 U.S.C. 102(a) as being anticipated by Hodgson et al. [WO 98/38326 (1998)].

Claim 15 is drawn to a method for synthesizing a double stranded nucleic acid molecule that contains information that represents computer-readable binary alphanumeric code.

Hodgson et al. teach a method for synthesizing a double stranded nucleic acid molecule that contains information that represents computer-readable alphanumeric code comprising all of the limitations recited in Claim 15. As regards the limitation that the double stranded nucleic acid molecule contain information that represents computer- readable binary alphanumeric code, this limitation is considered to be inherent to the double stranded nucleic acid molecule of Hodgson et al. in that each of the fragments is composed of nucleic acid sequence which codes for protein sequence. Please note that a nucleic acid sequence can be read in triplets (e.g. GGA) which in turn represents a particular amino acid of a protein sequence. In this example, GGA codes for Glycine (Gly or simply G). G in the binary code of ASCII is code 71 represented as 01000111. See for example http://en.wikipedia.org/wiki/ASCII#ASCII_printable_characters
Also, see, at least, for example, Fig. 8 and the description of Figure 8 on p.5.

Claim 19 is drawn to an embodiment of the method of Claim 15 wherein at least 10 double stranded fragments are hybridized together to produce the double stranded nucleic acid molecule.

Hodgson et al. teach this limitation. See at least for example p.12, beginning at about line 3.

Claim 20 is drawn to an embodiment of the method of Claim 15 wherein a plurality of double stranded nucleic acid molecules comprising a series of double stranded nucleic acid fragments are synthesized and linked together.

Hodgson et al. teach this limitation. See, at least, for example, Fig. 8 and the description of Figure 8 on p.5.

Claim 21 is drawn to a double stranded nucleic acid molecule that contains information that represents computer-readable binary alphanumeric code.

Hodgson et al. teach a double stranded nucleic acid molecule that contains information that represents computer-readable binary alphanumeric code. See, at least, for example, Fig. 8 and the description of Figure 8 on p.5. As regards the limitation that the double stranded nucleic acid molecule contain information that represents computer-readable binary alphanumeric code, this limitation is considered to be inherent to the double stranded nucleic acid molecule of Hodgson et al. in that each of the fragments is composed of nucleic acid sequence which codes for protein sequence Please note that a nucleic acid sequence can be read in triplets (e.g. GGA) which in turn represents a particular amino acid of a protein sequence. In this example, GGA codes for Glycine (Gly or simply G). G in the binary code of ASCII is code 71 represented as 01000111. See for example http://en.wikipedia.org/wiki/ASCII#ASCII_printable_characters

Also, please note that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey* , 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963).

Claim 23 is drawn to a library comprising a plurality of double stranded nucleic acid fragments.

Hodgson et al. teach a library comprising a plurality of double stranded nucleic acid fragments (i.e. the six fragments that are used to assemble the molecule shown in Figure 8). See, at least, for example, Fig. 8 and the description of Figure 8 on p.5.

5. **Claim(s) 21** is/are rejected under 35 U.S.C. 102(e) as being anticipated by Bancroft et al.[US 6,312,911 (2001)].

Claim 21 is drawn to a double stranded nucleic acid molecule that contains information that represents computer-readable binary alphanumeric code.

Bancroft et al. teach a double stranded nucleic acid molecule that contains information that represents computer readable binary alphanumeric code in the same way that Hodgson et al. teach a double stranded nucleic acid molecule that contains information that represents computer readable binary alphanumeric code. See the rejection above. See, at least, for example, Claim 5 and Figures 1A-1B. Admittedly, the double stranded nucleic acid molecule of Bancroft et al. is not produced by the same method. However, it is well established in US patent law that a product is not limited by the why it is made but rather by its structure. If the product in a claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

6. **Claim(s) 22** is/are rejected under 35 U.S.C. 102(b) as being anticipated by Tyagi et al. [Nature Biotechnology 16 :49-53 (JAN 1998)].

Claim 22 is drawn to a method of identifying at least one binary alphanumeric code unit contained in a double stranded nucleic acid molecule.

Tyagi et al. teach a method of identifying at least one binary alphanumeric code unit contained in a double stranded nucleic acid molecule. See, at least, for example, Figure 5 wherein these authors teach detecting SNPs. In the panel on the far left the probe is deigned to detect a T at the polymorphic position. T in the binary code of ASCII is code 84 represented as 01010100. Furthermore, in the panel on the right of Figure 5 the probe is deigned to detect a G at the polymorphic position. G in the binary code of ASCII is code 71 represented as 01000111. See for example http://en.wikipedia.org/wiki/ASCII#ASCII_printable_characters

35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a)** A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

CLAIM REJECTIONS UNDER 35 USC § 103

8. **Claim(s) 24** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodgson et al. [WO 98/38326 (1998)] as applied to Claims 15, 21, and 23 above and further in view of the Stratagene Catalog (1988).

Claim 24 is drawn to a kit for synthesizing a double stranded nucleic acid molecule that contains information that represents computer-readable binary alphanumeric code comprising a library of fragments as set for in Claim 15 and a ligase.

Hodgson et al. teach a library comprising a plurality of double stranded nucleic acid fragments that contain information that represents computer readable alphanumeric code (i.e. the six fragments that are used to assemble the molecule shown in Figure 8). In addition these authors teach a method of assembling the fragment of the library into a double stranded vector utilizing a ligase. See, at least, for example, Fig. 8 and the description of Figure 8 on p.5. Hodgson et al. do not teach a kit comprising these fragments with a ligase. However, as evidenced by the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. In addition the Stratagene catalog teaches the advantages of assembling a kit, such as, saving resources and reducing waste. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify

the teachings of Hodgson et al. with the teachings of the Stratagene Catalog wherein the reagents necessary to perform the method taught by Hodgson et al. are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits.

As regards the limitation "for synthesizing a double stranded nucleic acid molecule that contains information that represents computer-readable binary alphanumeric code, " this limitation is directed towards the intended use of the product and does not further limit the composition claimed. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey* , 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963).

CLAIM OBJECTIONS

9. **Claim(s) 16-17** are objected to because they are dependent upon a rejected independent base claim.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

10. Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are moot in view of the new ground(s) of rejection.

CONCLUSION

11. **Claim(s) 15-17 and 19-24** is/are rejected and/or objected to for the reason(s) set forth above.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM - 5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

ETHAN WHISENANT
PRIMARY EXAMINER

Art Unit 1634